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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,087	02/19/2004	Stephen T. Foley	82391	4761

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EXAMINER

HOLMES, REX R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/782,087	Applicant(s) FOLEY, STEPHEN T. C	
	Examiner Rex Holmes	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4, 7, 8, 12, 13, 18, 19, 21, 23, 26, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites "the stimulator" on the 3rd line, this is vague and unclear as to which stimulator is being discussed. Claim 1 further recites "an analysis" on 6th line, this is vague as no element has been set forth to analyze the sensed data.

5. Claim 4 uses the term "comprises", this is vague and unclear as it is dependant on claim 1, which already comprises certain components. It is noted that if the applicant wishes to add limitations, they can use "further comprises" and then recite how it is

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coupled to the other elements. Claim 4 also recites the limitation "said remote programmer" in the 3rd line of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 7 and 8 recite the language "for identifying", this is vague and unclear as it is not stated what is performing this function of "identifying".

7. Claims 12 and 13 recite the limitation "normal events" in the 2nd line of the claims. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 18 recites the limitation "the temporal offset" in the 1st line of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 19 recites the limitation "the temporal delivery" in the 1st line of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 20 recites the limitation "the polarity of the stimulation electrodes is programmable by a user", this limitation is vague as it is unclear what element is being programmed.

11. Claim 21 recites the limitation "the stimulator is programmed by a user", this limitation is vague and reads like a method step. It is suggested to delete "by a user".

12. Claim 23 is vague as it recites that it is a method for claim 22, while claim 22 is a system claim. Claim 23 further recites the limitation "two or more capacitors" in the 2nd line of the claim. The claim has not set forth that there are capacitors in the array. Claim 23 also recites "an array" in the 2nd line of the claim. This is vague as it is unclear if this is the same array or a different array from the one introduced on the 1st line of the claim. It is suggested to use "the array" inferentially included.

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13. Claim 26 recites the limitations "the sensed intrinsic waveforms" in the 1st line and "the external programmer" on the 2nd line of the claim. There is insufficient antecedent basis for these limitations in the claim. Claim 26 also recites that "the sensed intrinsic waveforms can be telemetered" this is vague as it is unclear which element performs this function.

14. Claim 27 recites the limitation, "the stimulator may incorporate one or a plurality of independently programmable stimulation or sensing channels". The term "may" is vague as the stimulator either has the channels or it does not. Claim 27 is also vague as it is unclear what element the channels connect to.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1-5, 7-10, 27 and 29-34 are rejected under 35 U.S.C. 102(b) as being anticipated by CHEN et al. (U.S. Pat. 5,690,691).

Regarding Claims 1-3 and 5, CHEN discloses a gastric pacemaker comprising a plurality of sensing electrodes (Figure 2, 52, 54, 56), a plurality of stimulation electrodes

(Figure 2, 42, 44, 46) contained in leads for coupling (Figure 2, 12, 14, 16), and an implantable gastric stimulator (Figure 2, 10). CHEN further discloses that the electrodes are positioned at different locations of the stomach wall (Figure 2, 42, 44, 46), and are controlled by an electronic controller that is programmable (Column 5, Lines 39-42).

Regarding Claims 7-10 and 27, CHEN discloses that the sensing electrodes communicate with the stimulator identifying the frequency, strength and timing of the intrinsic electric activity (Column 5, Lines 49-51; Column 5, Lines 55-63). CHEN further discloses that the stimulator looks at the activity to see if it is a slow wave or a peristaltic wave, and based on this it stimulates the organ (Column 6, Lines 43-53). It also discloses that the stimulator can have multiple electrodes that are each individually controlled (Column 6, Lines 19-23).

Regarding Claims 29, and 31-34, CHEN discloses a method for gastric stimulation comprising, sensing the activity (Column 5, Lines 49-51; Column 5, Lines 55-63), determining the activity and when to apply the stimulation and then stimulating to disrupt normal gastric activity (Column 5, Lines 60-67; Column 6, Lines 1-10).

17. Claims 1-5, 7-10, 27, and 29-34 are rejected under 35 U.S.C. 102(e) as being anticipated by FAMILONI (U.S. Pat. 6,327,503).

Regarding Claims 1-5, FAMILONI discloses a gastric pacemaker comprising a plurality of sensing electrodes (Figure 1, 4), a plurality of stimulation electrodes (Figure 1, 5) contained in leads for coupling (Column 4, Lines 56-59), and an implantable gastric stimulator (Figure 1, 3). FAMILONI further discloses that the electrodes are positioned at different locations of the stomach wall (Figure 1), and are controlled by an

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electronic controller that is programmed using an inductive coupling methodology or radio communication methodology (Column 12, Lines 18-22).

Regarding Claims 7-10 and 27, FAMILONI discloses that the sensing electrodes communicate with the stimulator identifying the frequency, strength and timing of the intrinsic electric activity (Column 10, Lines 35-44). FAMILONI further discloses that the stimulator looks at the activity to see if it is a slow wave or a peristaltic wave, and based on this it stimulates the organ (Column 10, Lines 16-19). It also discloses that the stimulator can have multiple electrodes that are each individually controlled (Column 5, Lines 26-30).

Regarding Claims 29, and 31-34, FAMILONI discloses a method for gastric stimulation comprising, sensing the activity (Column 3, Lines 42-45), determining the activity and when to apply the stimulation and then stimulating to disrupt normal gastric activity (Column 6, Lines 45-53).

It is noted that classifying an activity as normal is in itself arbitrary. In this instance the normal activity is the activity that triggers the stimulation. Based on this any activity that is considered to be a trigger is normal activity. FAMILONI discloses several triggers and any of them can be considered normal activity.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 6, 11-26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN as applied to claims 1 and 7 above, and further in view of GORDON (U.S. Pat. 6,892,278).

20. CHEN discloses a gastrointestinal stimulation device as described in detail above, and further discloses that the stimulator is triggered on classified events and the stimulation is delivered to the stomach in the areas where the intrinsic activity was sensed (Column 3, Lines 34-50). CHEN further discloses that the electrodes are spaced spatially throughout the stomach (Figure 2, 42, 44, 46). CHEN further discloses that the stimulation is delivered with a temporal offset that can be determined by the controller, or be programmed by a user (Column 3, Lines 34-50). CHEN also discloses that the stimulator can be to accommodate for multiphase stimulation (Column 3, Lines 34-45).

21. CHEN further discloses that when the output pulse is to be delivered, its amplitude, pulse width, frequencies, and duration can be programmed and controlled by the controller (Column 3, Lines 34-50). CHEN discloses that the pulse amplitudes, pulse durations, pulse periods, and relative pulse phasing among the electrodes can be controlled to stimulate the organ. (Column 3, Lines 34-45). However, CHEN does not teach a power conservation condition or a way to save sensed data.

22. GORDON teaches a power conservation condition that takes into account the time of day and in the absence of a triggering activity (Column 2, Lines 62-67 and Column 3, Lines 1-5). GORDON further discloses that the controller contains an internal

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storage device and the data can be telemetered using an inductive coupling methodology or radio communication methodology (Column 15, Lines 1-9). (Column 10, Lines 44-58). (Column 10, Lines 44-58).

23. Regarding Claims 6 and 11-21, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of CHEN with the power conservation of GORDON in order to increase the life of the stimulation device, increase the life of the battery, and to increase the overall quality of life of the patient.

24. Regarding Claims 22 and 24, CHEN disclosed the claimed invention except for the exact values of amplitude, pulse width, frequencies, and duration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the values of the amplitude, pulse width, frequencies, and duration as taught by CHEN, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

25. Regarding Claims 23 and 25-26, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the stimulation device of CHEN with the power conservation of GORDON to provide a stimulation device with optimal stimulation and the ability to store and export the recorded data to an external programmer to further analyze the data with a processor that is more powerful than the one in the stimulator.

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26. Regarding Claim 30, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation method of CHEN with the activity storage method of GORDON in order to save the data so that it could be reviewed to review the progress of the method and to help improve the efficiency of the stimulation.

27. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN as applied to Claims 1 and 7 above, and further in view of GORDON or in view of GORDON and WERNICKE (U.S. Pat. 5,188,104).

28. CHEN discloses a gastrointestinal stimulation device as described in detail above using programmable amplitude and frequency that meets the intended use recitation of being for a nerve. However, CHEN does not teach a power conservation condition or; alternatively stimulation of a nerve.

29. GORDON teaches a power conservation condition that takes into account the time of day and in the absence of a triggering activity. (Column 10, Lines 44-58). However, GORDON does not teach the stimulation of a nerve.

30. WERNICKE discloses the stimulation of the vagus nerve for the treatment of eating disorders such as compulsive over-eating, bulimia, or anorexia nervosa (Column 1, Lines 44-56). WERNICKE further discloses the various ranges of parameters for the output waveform (Column 13, Lines 60-67).

31. Regarding Claim 28, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the stimulation device of CHEN with the power conservation of GORDON and with the nerve stimulation of

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WERNICKE to provide a stimulation device with a long lasting battery that could increase or decrease the digestive process by stimulating both organs and nerves.

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Rex Holmes


George Evanisko

Primary Examiner

04/06